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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/013,895 01/27/98 NI

J PF355

EXAMINER

HM12/1116

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KAUFMAN, C	
ART UNIT	PAPER NUMBER

1646

25

DATE MAILED:

11/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/013,895

Applicant(s)

NI ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-31, 35-38, 40-45, 47-51, 53, 55-58, 60-65, 67-70, 72, 75, 76, 78-81, 84-89, 91-93, 95-105, 108, 109, 111-114, 118, ... is/are allowed.
- 6) ☒ Claim(s) 32, 33, 39, 46, 59, 66, 77, 94, 110, 130, 137, 148, 169, 176, 192, 194, 195, 198-208 and 214 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

The preliminary amendment filed 8/31/00 has been entered.

Continued Prosecution Application

The request filed on 8/31/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/013,895 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

Applicant's election with traverse of claims 46, 66, 137, 176, 192 and 207 in Paper No. 24 is acknowledged. The traversal is on the ground(s) that the publications that disclose host cells comprising TNF-family receptors normally also disclose that such host cells are useful to screen for ligand binding and so the search of those claims would not present a serious burden. This is not found persuasive because as stated in the previously Office action, the method is classified differently from the host cell, nucleic acid and protein (435/7.2) and requires a different search than that required for the nucleic acid, vector and host cell. Publications disclosing host cells will not necessarily disclose ligand screening assays because host cells are often exclusively used for the amplification of nucleic acid and simple production of protein without screening assays set forth. For example, the GenBank reference previously relied upon teaches a host cell with no ligand binding. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

However, under *In re Ochia*, Applicants requested rejoinder of the claims (see response on page 12). In light of this and the fact that the application is receiving a first action on the merits after CPA, a process claim dependent on allowable product claim will be rejoined and examined. Such rejoinder is *not* tantamount to a withdrawal of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

The rejection of claims under 35 USC 102 is withdrawn in view of the amendment to the claims, and it is noted that while "N" appearing in the GenBank polynucleotide represents a nucleotide, it is not clear which nucleotide and so what would be encoded cannot be determined. As it appears that the DNA of the instant application was not isolated from the same source as that of the GenBank reference, one cannot say that it would reasonably be expected that the "N" would represent the same nucleotide present in SEQ ID NO:1.

The rejection of claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims. Note that a new rejection appears below.

The rejection of claims under 35 USC 112, first paragraph, set forth on p. 8, lines 12-22, of paper #12 is withdrawn in view of enablement due to the satisfaction of the biological deposit requirement.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 160-161 are objected to because of the following informalities: "polypeptide bind an" is incorrect grammar. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 32, 39, 46, 59, 66, 77, 94, 110, 130, 137, 148, 169, 176, ¹⁹²194, 195, 202, 207, 214 and dependent claims 33, 198-201, 203-206 and 208 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 59, 77, 94, 110, 130, 148, 169, 202 and 214 are indefinite because they are drawn to a method of producing a vector, yet the starting material is a vector. The method is then circular and one does not produce anything.

Claims 46, 66, 137, 176, ¹⁹²and 207 recite the limitation "said ligand" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "said reference nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 176 is indefinite because it depends on a cancelled claim.

Claims 194 and 195 are confusing. Claim 194 is unclear because it cannot be determined in light of claim 195 if hybridization must occur under the stated conditions to a nucleic acid consisting of nucleotides complementary to 88-732. If claim 194, which claim 195 depends on, must hybridize to the complement of nucleotides 88-732 of SEQ ID NO:1, wouldn't said nucleic acid of claim 194 also necessarily hybridize under the recited conditions to the complement of nucleotides 412-681? If yes, then claim 195 is not further limiting. If no, then the polynucleotide of claim 195 would not be enabled as it must encode a polypeptide which binds TRAIL (see 112, first paragraph rejection below).

Claim Rejections - 35 USC § 112, First Paragraph

Claim 195 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide that hybridizes to the complement of nucleotides 412-681 of SEQ ID NO:1 and is not limited by a function, or for the polynucleotide of claim 194 (i.e., hybridizes to complement of 88-732 of SEQ ID NO:1), does not reasonably provide enablement for a polynucleotide that hybridizes to the complement of nucleotides 412-681 of SEQ ID NO:1 and is required to bind TRAIL. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Nucleotides 412-681 of SEQ ID NO:1 encode amino acids about 132-221 (half the length of the extracellular domain (ECD)). The ECD of SEQ ID NO:2 is amino acids about 24-238 (p. 10, third paragraph of specification). It is not disclosed what portion of the ECD is responsible for ligand binding. Ligand binding is a complex process involving not only the actual amino acids that contact the ligand, but also other amino acids in the domain responsible for the necessary three-dimensional conformation of the contacting amino acids. This complexity is exemplified for beta-adrenergic receptor by Strader et al., (FASEB J 3:1825, 1989). The instant claims only require that the nucleic acid hybridize to the complement of nucleotides 412-681 of SEQ ID NO:1 and that it encodes a polypeptide that binds TRAIL. The hybridizing nucleic acid

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does not need to be highly identical to the nucleic acid of SEQ ID NO:1 because of the nature of hybridization. It also does not need to encode the full ECD. It is unpredictable how similar and how long the encoded polypeptide needs to be compared to ECD of SEQ ID NO:2 to bind TRAIL. There are no examples of anything less than the full ECD binding TRAIL. The claim has significant breadth because of the structural breadth allowed by the hybridization conditions. It would require undue experimentation to make the invention commensurate in scope with the claim.

Conclusion

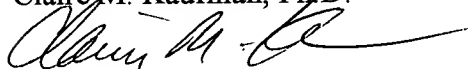
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

November 14, 2000